JUN 12 2003

Appendix I, Page 1 (added)

510(k) SUMMARY FOR

K030994
NON-STERILE ORANGE COLORED POWDERED LATEX PATIENT EXAMINATION GLOVES WITH & WITHOUT ORANGE/VANILLA SCENTS AND WITH A PROTEIN LABELING CLAIM (<200ug/g)

Contains 200 mcgm or less of total Water extractable protein per gram.

Submitted for: **SGMP COMPANY, LTD.**

Submitted by: **TUCKER & ASSOCIATES**
Official Correspondent for SGMP COMPANY, LTD.
JANNA P. TUCKER, President – CEO
198 Avenue de la D'emerald
Sparks, NV 89434-9550
Phone: 775-342-2612
Fax: 775-342-2613
E-Mail: Tuckerjan@aol.com

This device is substantially equivalent to K000671, which is another of SGMP's Colored, and/or scented powdered latex gloves with protein labeling (<200ug/g).

Revised 06-04-03

Appendix I

2. Physical Properties (ASTM-D3578-01aE2 Standard Specification for Latex Exam Gloves)

LOT #	TENSILE STRENGTH				ULTIMATE ELONGATION			
0226	UNAGED		AGED		UNAGED		AGED	
TESTED	SGMP	ASTM	SGMP	ASTM	SGMP	ASTM	SGMP	ASTM
X-SMALL	24.1	14.0	27.0	14.0	820	700	900	500
SMALL	24.8	14.0	24.4	14.0	830	700	870	500
MEDIUM	25.8	14.0	24.2	14.0	820	700	890	500
LARGE	22.4	14.0	21.0	14.0	800	700	820	500

3. Water Tight Test Data

BATCH NUMBER	DATE TESTED	SAMPLING SIZE	LEAK STATUS	NUMBER LEAKED
Unaged Smpl				
0226 XS	10 Feb 03	125	Yes	1
S		125	No	0
M		125	Yes	1
L		125	Yes	1
Aged Smpl				
0226 XS	18 Feb 03	125	No	0
S		125	Yes	1
M		125	Yes	2
L		125	No	0

The above figures are within the ASTM D-3578-01aE2 requirements for latex exam gloves of 2.5% AQL.

4. Biocompatibility

BIOCOMPATIBILITY TESTS — Test results indicate that the gloves passed the biocompatibility tests for gloves.

5. Residual Protein Level

TESTS	FDA ALLOWABLE LEVEL	CLAIMED LEVEL
ASTM D 5712-99	-	< 200 µg/g Range: 98 –112 µg/g Mean: 101 µg/g

Revised 5-27-03
JE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2003

SGMP Company, Limited
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue de la D' emerald
Sparks, Nevada 89434-9550

Re: K030994
Trade/Device Name: Non-Sterile Orange Colored Powdered Latex Examination Gloves with & without Orange/Vanilla Scents and with a Protein Labeling Claim. Contains 200 Micrograms or Less of Total Water Extractable Protein Per Gram
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: May 27, 2003
Received: May 29, 2003

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: **SGMP COMPANY, LTD.**

510(k) NUMBER: K030994

DEVICE NAME: **NON-STERILE ORANGE COLORED POWDERED LATEX PATIENT EXAMINATION GLOVES WITH & WITHOUT ORANGE/VANILLA SCENTS AND WITH A PROTEIN LABELING CLAIM (<200uG/G)** Contains 200 mg or less of total Water ~~per gram~~ extractable protein per gram

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030994

Revised 06-04-03